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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT PAPER NUMBER

1634

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/055,878

Applicant(s)
Liu

Examiner
Arun Chakrabarti

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 4, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-89 is/are pending in the application.
- 4a) Of the above, claim(s) 54-87 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-53, 88, and 89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1 6) ☒ Other: Detailed Action

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, corresponding to claims 1-53, 88, and 89, in Paper No. 0303, is acknowledged. The traversal is on the ground(s) that there is no burden to examine claims of Groups II and III along with claims of Group I. This is not found persuasive because as it is made clear in the restriction requirement that examination of Groups II and III will require the search of not only 1228 patents of Group I under the class 536, subclass 22.1 but also 3352 patents of Group II under the class 435, subclass 91.1, and in addition 15505 patents of Group III under the class 435, subclass 6. This is prima facie evidence of the burden of search, which is not rebutted.

The requirement is still deemed proper and is therefore made FINAL.

ZB

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 1-14, 17-35, 88, and 89 are rejected under 35 U.S.C. 102(a) as being anticipated by Liu (PCT International Publication Number WO 01/26799 A1) (April 19, 2001).

Liu teaches an article (Abstract) comprising:

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at least two plates, wherein each plate defines a plurality of cylindrical capillaries, each capillary having a pair of opposed ends, with at least one capillary comprising a reagent inlet and at least one capillary comprising a reagent outlet (Claim 1 and Figures 1-5, and Page 4, lines 3-15);

the plate further defining a plurality of channels oriented substantially perpendicularly to the capillaries and configured to selectively operably connect adjacent capillaries so as to form a continuous passage from the reagent inlet to the reagent outlet, the channels being further configured to direct the reagent into a capillary at one end thereof and from the capillary at the other end thereof such that the reagent flows through substantially the length of the capillary and serially through all of the capillaries defined by the plate (Claim 1 and Figures 1-5, and Page 4, lines 3-15); and

wherein the plates are positioned to substantially align the plurality of cylindrical capillaries from a first plate and a second plate (Claim 1 and Figures 1-5, and Page 4, lines 3-15).

Liu teaches an article, wherein the plates are substantially flat and further comprise a medial member disposed between and operably engaging opposing distal members (Claim 2)

Liu teaches an article, wherein the medial member defines the capillaries and the channels (Claim 3).

Liu teaches an article, wherein the medial member defines the capillaries and the distal member defines the channels (Claim 4).

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Liu teaches an article, further comprising at least one securing member configured to secure the distal members to the medial member in sealing relation (Claim 5).

Liu teaches an article, wherein the capillaries are disposed in an array (Claim 6).

Liu teaches an article, wherein the capillaries are between about 5 microns and about 1000 microns in diameter (Claim 7).

Liu teaches an article, wherein the capillaries are each configured to have a voltage applied across the ends thereof so as to form an electrostatic pump capable of causing the reagent to flow in a corresponding direction therebetween (Claim 8).

Liu teaches an article, wherein the voltage is reversible such that the flow of the reagent is capable of being selectively reversed (Claim 9).

Liu teaches an article, wherein the capillaries are each configured to have a biosample deposited on the inner wall of the capillary such that the biosample is assayed by a reagent flowing through the capillary (Claim 10).

Liu teaches an article, wherein the plate is comprised of at least one of a semiconductor material and a polymeric material (Claim 11).

Liu teaches an article, wherein the plate is comprised of at least one silicon and an injection-moldable polymeric material (Claim 12).

Liu teaches an article, wherein the plate is comprised of a polymeric material when the plate defines a capillary density up to about 2,000 capillaries per square centimeter (Claim 13).

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Liu teaches an article, wherein the plate is comprised of a semiconductor material when the plate defines a capillary density between about 2,000 capillaries per square centimeter and about 2,000,000 capillaries per square centimeter. (Claim 14).

Liu teaches an article, which further comprises a volume-reducing arrayer apparatus, wherein the volume-reducing arrayer apparatus (Figure 4) comprises :

at least one plate disposed between the reservoir and the substrate and in communication with the reservoir, the at least one plate defining at least one plate capillary extending toward the substrate, the at least one plate capillary being configured to have a reduced volume with respect to the reservoir so as to receive a portion of the solution therefrom; and

a flow control device disposed between the at least one plate and the substrate and in communication with the at least one plate, the flow control device defining at least one flow control capillary corresponding to the at least one plate capillary and extending toward the substrate, the at least one flow control capillary being configured to have a reduced volume with respect to the at least one plate capillary, the flow control device being further configured to control the flow of a predetermined amount of the solution through the at least one flow control capillary, from the at least one plate capillary to the substrate (Figure 4, and Page 11, lines 6-21).

Liu teaches an article, wherein the at least one flow control capillary is configured to have a diameter smaller than the diameter of the plate capillary such that the smaller diameter of the flow control capillary provides a reduced volume per unit length with respect to the plate capillary (Page 11, line 23 to page 12, line 4).

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Liu teaches an article, wherein the at least one plate defines a plurality of plate capillaries arranged in an array (Figure 5, and Page 12, lines 5-18).

Liu teaches an article, wherein the flow control device defines a plurality of flow control capillaries arranged in an array corresponding to the plate capillary array (Figure 6, Page 12, lines 19-33).

Liu teaches an article, wherein the at least one of the plate and the flow control device defines a plurality of channels configured such that each channel operably connects one plate capillary in the plate capillary array to one corresponding to flow control capillary in the flow control device array (Page 13, lines 3-15).

Liu teaches an article, wherein the at least one plate comprises a first plate and a second plate, with each plate having a solution entrance surface and a solution exit surface, and wherein the solution exit surface of the first plate is configured to operably engage the solution entrance surface of the second plate (Figures 6-7, and Page 13, lines 16-30).

Liu teaches an article, wherein the first plate defines a plurality of first plate capillaries arranged in an array, the array further comprising a first portion of first plate capillaries and a second portion of first plate capillaries (Figures 6-7).

Liu teaches an article, wherein the solution exit surface of the first plate further defines a plurality of first plate channels, with each first plate channel extending from one capillary in the first portion of first plate capillaries to a corresponding indentation in a plurality of first plate

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indentations also defined by the solution exit surface of the first plate, the first plate indentations also being arranged in an array (Figure 7A, and Page 14, lines 4-13).

Liu teaches an article, wherein the second plate defines a plurality of second plate capillaries arranged in an array, the array further comprising a first part of the second plate capillaries corresponding to the second portion of the first plate capillaries and a second part of second plate capillaries corresponding to the first plate indentations (Figure 5).

Liu teaches an arrayer apparatus, wherein the solution exit surface of the second plate further defines a plurality of second plate channels, with each second plate channel extending from one capillary in the first part of the second plate capillaries to a corresponding indentation in a plurality of second plate indentations also defined by the solution exit surface of the second plate, the second plate indentations also being arranged in an array (Figures 6-7).

Liu teaches an article, wherein the flow control device defines a plurality of flow control capillaries arranged in an array, the flow control capillaries corresponding to the second plate indentations and to the second part of the second plate capillaries corresponding to the first plate indentations (Figure 4, and Page 11, lines 6-15).

Liu teaches an article, further comprising a stamper head disposed between the flow control device and the substrate and in communication with the flow control device, the stamper head defining a plurality of stamper capillaries arranged in an array and corresponding to the flow control capillaries, the stamper head being configured to channel the predetermined amount of the solution from the flow control device to the substrate (Page 11, lines 22-31).

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Liu teaches an article, wherein the stamper capillaries are configured to have a reduced volume with respect to the flow control capillaries (Page 11, lines 27-29).

Liu teaches an article, wherein the stamper capillaries are each configured to have a diameter smaller than diameter of each flow control capillary such that smaller diameter of the stamper capillary provides a reduced volume per unit length with respect to the flow control capillary (Page 11, lines 27-29).

Liu teaches an article, wherein the flow control device comprises at least one of a pump and a valve (Figure 4, and Page 11, lines 6-17).

Liu teaches an article, wherein the flow control capillaries are each configured to have a high voltage applied between two points along the length thereof so as to form an electrostatic pump capable of causing the solution to flow there along (Figure 4, and Page 11, lines 6-17).

Liu teaches an article, wherein the voltage is capable of being adjusted so as to form an electrostatic valve capable of selectively preventing flow of the solution through the flow control capillaries and such that only a predetermined amount of the solution flows through the flow control capillaries (Figure 4, and Page 11, lines 6-31).

Liu teaches an article, wherein the at least one of the flow control device and at least one plate are comprised of silicon ((Figure 7, and Page 13, lines 31-33, and claim 11).

Liu teaches a 4D biochip, comprising:

m 3D biochip means, wherein m is an integer from 2 to 100,000 wherein each pair of adjacent 3D biochip means are operably connected by aligning capillaries present in one of the

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pair with capillaries present in the other of the pair (Claims 1-14 and Figures 1-7, and page 3, line 23 to page 6, line 5).

Liu teaches a 4D biochip, wherein each of the m3D biochip means contains n capillaries passing therethrough, wherein n is an integer from 2 to 100, 000 (Claims 1-14 and Figures 1-7).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being obvious over Liu et al.

(PCT International Publication Number WO 01/26799 A1) (April 19, 2001).

Liu teaches an article of claims 1-14, 17-35, 88, and 89 as described above.

Liu does not teach an article, which comprises at least 10 to 100 plates.

However, it is *prima facie* obvious that selection of the specific number of plates represents routine optimization with regard to the requirement of high throughput applications and methods of using biochips, which routine optimization parameters are explicitly recognized to an ordinary practitioner in the relevant art. As noted *In re Aller*, 105 USPQ 233 at 235,

More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable

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ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the the number of plates selection performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

6. Claims 36-53 are rejected under 35 U.S.C. 103(a) as being obvious over Liu et al. (PCT International Publication Number WO 01/26799 A1) (April 19, 2001) in view of Holley (U.S. Patent 4,085,780) (April 25, 1978).

Liu teaches an article of claims 1-14, 17-35, 88, and 89 as described above.

Liu does not teach an article comprising

a reservoir for containing the solution;

at least one arrayer block disposed between the reservoir and the substrate and in communication with the reservoir, the at least one arrayer block defining at least one arrayer capillary extending toward the substrate, the at least one arrayer capillary being configured to have a reduced volume with respect to the reservoir so as to receive a portion of the solution therefrom.

Holley teaches an article comprising

a reservoir for containing the solution;

at least one arrayer block disposed between the reservoir and the substrate and in communication with the reservoir, the at least one arrayer block defining at least one arrayer

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capillary extending toward the substrate, the at least one arrayer capillary being configured to have a reduced volume with respect to the reservoir so as to receive a portion of the solution therefrom (Figure 1, and Column 1, lines 59-66).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine an article comprising

a reservoir for containing the solution;

at least one arrayer block disposed between the reservoir and the substrate and in communication with the reservoir, the at least one arrayer block defining at least one arrayer capillary extending toward the substrate, the at least one arrayer capillary being configured to have a reduced volume with respect to the reservoir so as to receive a portion of the solution therefrom of Holley in the article of Liu et al, since Holley states "The invention is accordingly concerned with the provision of an apparatus for and a method of dispensing liquid to wells of a multi-well tray in a quick and inexpensive way (Column 1, lines 24-27)". Further motivation is provided by Liu as Liu states, "The present invention relates to biological chips for conducting parallel biosample assays and, more particularly, to a biological chip defining a channeled capillary array for conducting large-scale parallel biosample assays and associated methods of use and fabrication (Page 1, lines 2-5)". An ordinary practitioner would have been motivated to substitute and combine an article comprising

a reservoir for containing the solution;

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at least one arrayer block disposed between the reservoir and the substrate and in communication with the reservoir, the at least one arrayer block defining at least one arrayer capillary extending toward the substrate, the at least one arrayer capillary being configured to have a reduced volume with respect to the reservoir so as to receive a portion of the solution therefrom of Holley in the article of Liu, in order to achieve the express advantages, as noted by Holley, of an invention that provides the provision of an apparatus for and a method of dispensing liquid to wells of a multi-well tray in a quick and inexpensive way and also to achieve the express advantages, as noted by Liu, of an invention that relates to biological chips for conducting parallel biosample assays and, more particularly, to a biological chip defining a channeled capillary array for conducting large-scale parallel biosample assays and associated methods of use and fabrication.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph. D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703)746-4979.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

April 15, 2003

Arun K. Chakrabarti
ARUN K. CHAKRABARTI
PATENT EXAMINER